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10/666,502	09/19/2003	James L. Chappuis	050313-1110	8958

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EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/666,502

Applicant(s)

CHAPPUIS, JAMES L.

Examiner

Fangemonique Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/28/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on November 28, 2005.

The Examiner acknowledges the amendments to claims 1-3 and the addition of claims 4-15. Claims 1-15 are pending.

Claim Objections

2. Claim 14 is objected to because of the following informalities:

- a. At line 8 of claim 2, it is suggested to replace the word “means” with the word --device--.
- b. At line 1 of claim 4, it is suggested to insert the word --primary-- before “members”.
- c. At line 1 of claim 7, it is suggested to insert the word --primary-- before “members”.
- d. At line 1 of claim 6, it is suggested to replace the word “device” with the word --means--.
- e. At line 2 of claim 14, it is suggested to modify the word “iincludes” to read -- includes--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 2 recites the limitation "said load measuring means" in line 7. There is no prior mention of a load measuring means in claim 2. Therefore, there is insufficient antecedent basis for this limitation in the claim.
6. Claim 9 recites the limitation "the load measuring device" in line 1. There is no prior mention of a load measuring device in claim 9 or in any claim from which claim 9 depends. Therefore, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

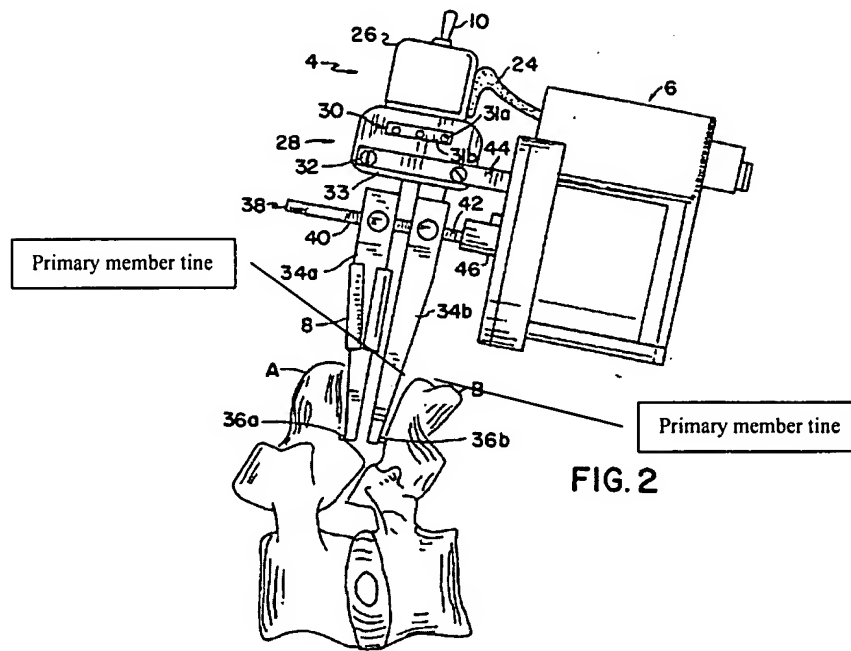
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (U.S. Patent Number 4,899,761).

In regard to claims 1, 2, 6 and 9, Brown et al. disclose an apparatus (1) that comprises a load measuring means for measuring load between two points and a distance measuring means for measuring distance between said two points (col.3; col.4 lines 1-4). The apparatus (1) further comprises a pair of primary members (34a, 34b) being hingedly

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fixed together. The primary members of the Brown et al. device have contact tines as shown in Fig. 2 below.



The apparatus measures the load of the contact tines as well as the distance between the contact tines (col.3; col.4 lines 1-4). The Brown et al. apparatus is adapted to engage a pair of intervertebral bodies to measure a load therein and said a distance therebetween as depicted in Fig. 2. The load measuring means of the Brown et al. device includes a strain gauge (col. 7, lines 7-19).

In regard to claim 3, use of the Brown et al. apparatus consist of a method comprising inserting contact tines of the apparatus between adjacent vertebrae. Once the device is appropriately positioned, the user would measure a load and distance between the adjacent vertebrae of interest.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent Number 4,899,761) in view of Nicholas et al. (U.S. Patent Number 5,782,859).

In regard to claims 4 and 7, Brown et al. disclose the features of the Applicant's invention as described above. Brown et al. do not disclose what type of material is used to make the device. Nicholas et al. disclose a surgical instrument used for endoscopic or laparoscopic procedures. The devices include a handle portion, an articulation section and upper and lower arm members. The instrument disclosed by Nicholas et al. is made of stainless steel or a similar material. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to use an instrument designed to make contact with an internal portion of a body for applying and measuring a load between two points, similar to that disclosed by Brown et al., made of a sturdy alloy such as stainless steel, similar to that disclosed by Nicholas et al., to provide a durable instrument with a reduced chance of wear due to rusting.

11. Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent Number 4,899,761) in view of Frey et al. (U.S. Patent Application Publication Number 2002/0165550 A1).

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In regard to claims 10-15, Brown et al. disclose the features of the Applicant's invention as described above including, a step of determining the desirability of a spinal fusion procedure; however Brown does not expressly disclose a step of inserting a fusion device. Furthermore, Brown et al. do not disclose an apparatus whose use includes inserting a fusion device having a determined thickness. Frey et al. disclose devices and instruments used for implant insertion through a posterior lateral opening to the disc space. Frey et al. disclose a method comprising the steps of inserting a fusion device or cage, which can be packed with bone growth material, into a disc space D1 (paragraph [0140]). The fusion device has a predetermined thickness, which upon implanting into the patient, helps absorb and evenly distribute the load while stabilizing the spine. Frey et al. discuss the implant material being made of natural autograft or synthetic or natural bone graft substitutes (paragraph [0182]). It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to design a load measuring means, similar to that disclosed by Brown et al., to incorporate a fusion device, similar to that disclosed by Frey et al., to allow surgeon to implant desired material into the region of interest providing additional utility to the load measuring device.

12. Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (U.S. Patent Number 4,899,761) in view of Howell (U.S. Patent Number 5,570,706).

In regard to claims 5 and 8, Brown et al. disclose the features of the Applicant's invention as described above. Brown et al. do not disclose primary members being hingedly fixed together with a spring loaded hinge. Howell discloses an improved method of

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reconstructing a torn anterior cruciate ligament. An instrument disclosed by Howell for use during executing the method includes a spring loaded strain gauge tensiometer. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to design a load measuring means, similar to that disclosed by Brown et al., to incorporate a spring loaded mechanism, similar to that disclosed by Howell, to provide another way to lock the device at a desired position while maintaining a constant force on the region of interest.

Response to Arguments

13. In regard to claim 1, Applicant has amended the claim to include the limitation "a pair of primary members hingedly fixed together". However, the claim does not clearly state the nature of the connection between the primary members. The claim indicates the primary members are hingedly fixed together but does not clarify whether or not there are additional members included to allow fixation. The claim does not require that the fixation be located at a single common point or axis. Brown et al. disclose a pair of primary members pivotally fixed together at pivots 30 on frame 28 (see col. 3, lines 47-60 and col. 6, lines 48-54). Therefore, the amended claim does not overcome the original rejection. As stated in the Office Action August 22, 2005, Brown et al. disclose an apparatus (1) that comprises a load measuring means for measuring load between two points and a distance measuring means for measuring distance between said two points (col.3; col.4 lines 1-4). The apparatus (1) further comprises a pair of primary members (34a, 34b) being pivotally connected at frame (28) (col. 6, lines 48-54). The rejection stands and as a result, all claims dependent from claim 1 are also rejected.

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14. In regard to claims 2 and 3, Applicant indicates the Brown et al. reference cited does not meet the limitation “a pair of primary members being hingedly fixed together” however the Examiner respectfully disagrees. Brown et al. specifically describe a pair of primary members (34a, 34b) being pivotally connected at frame (28) (col. 6, lines 48-54). The amendments made to claims 2 and 3 do not overcome the original rejection of the Office Action dated August 22, 2005 for the same reasons as stated above. Therefore, the rejection stands. Any claim depending from claims 2 and 3 are also rejected.

15. Applicant's arguments filed on November 28, 2005 have been fully considered but they are not persuasive.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


CHARLES MARMOR
PRIMARY EXAMINER

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